



Year: 2020

Validation of the Academic Research Consortium for High Bleeding Risk (ARC-HBR) criteria in patients undergoing percutaneous coronary intervention and comparison with contemporary bleeding risk scores

Ueki, Yasushi ; Bär, Sarah ; Losdat, Sylvain ; Otsuka, Tatsuhiko ; Zanchin, Christian ; Zanchin, Thomas ; Gragnano, Felice ; Gargiulo, Giuseppe ; Siontis, George C M ; Praz, Fabien ; Lanz, Jonas ; Hunziker, Lukas ; Stortecky, Stefan ; Pilgrim, Thomas ; Heg, Dik ; Valgimigli, Marco ; Windecker, Stephan ; Räber, Lorenz

Abstract: AIMS The Academic Research Consortium for High Bleeding Risk (ARC-HBR) defined consensus-based criteria for patients at high bleeding risk (HBR) undergoing percutaneous coronary intervention (PCI). We aimed to validate the ARC-HBR criteria for the bleeding outcomes using a large cohort of patients undergoing PCI. **METHODS AND RESULTS** Between 2009 and 2016, patients undergoing PCI were prospectively included in the Bern PCI Registry. Patients were considered to be at HBR if at least one major criterion or two minor criteria were met. The primary endpoint was Bleeding Academic Research Consortium (BARC) 3 or 5 bleeding at one year; ischaemic outcomes were assessed using the device-oriented composite endpoints (DOCE) of cardiac death, target vessel myocardial infarction, and target lesion revascularisation. Among 12,121 patients, those at HBR (n=4,781, 39.4%) had an increased risk of BARC 3 or 5 bleeding (6.4% vs 1.9%; $p<0.001$) and DOCE (12.5% vs 6.1%; $p<0.001$) compared with those without HBR. The degree of risk and prognostic value were related to the risk factors composing the criteria. The ARC-HBR criteria had higher sensitivity than the PRECISE-DAPT score and the PARIS bleeding risk score (63.8%, 53.1%, 31.9%), but lower specificity (62.7%, 71.3%, 86.5%) for BARC 3 or 5 bleeding. **CONCLUSIONS** Patients at HBR defined by the ARC-HBR criteria had a higher risk of BARC 3 or 5 bleeding as well as DOCE. The bleeding risk was related to its individual components. The ARC-HBR criteria were more sensitive for identifying patients with future bleedings than other contemporary risk scores at the cost of specificity. ClinicalTrials.gov Identifier: NCT02241291 **Visual summary.** According to the ARC-HBR criteria, 40% of patients undergoing PCI were at HBR. Compared with patients without HBR, those at HBR had an increased risk of BARC 3 or 5 bleeding (6.4% vs 1.9%, $p<0.001$). There was a gradual risk increase for BARC 3 or 5 bleeding and DOCE as a function of the ARC-HBR score. BARC: Bleeding Academic Research Consortium; DOCE: device-oriented composite endpoints; HBR: high bleeding risk.

DOI: <https://doi.org/10.4244/EIJ-D-20-00052>

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ZORA URL: <https://doi.org/10.5167/uzh-191739>

Journal Article

Published Version

Originally published at:

Ueki, Yasushi; Bär, Sarah; Losdat, Sylvain; Otsuka, Tatsuhiko; Zanchin, Christian; Zanchin, Thomas; Gragnano, Felice; Gargiulo, Giuseppe; Siontis, George C M; Praz, Fabien; Lanz, Jonas; Hunziker, Lukas; Stortecky, Stefan; Pilgrim, Thomas; Heg, Dik; Valgimigli, Marco; Windecker, Stephan; Räber, Lorenz (2020). Validation of the Academic Research Consortium for High Bleeding Risk (ARC-HBR) criteria in patients undergoing percutaneous coronary intervention and comparison with contemporary bleeding risk scores. *EuroIntervention*, 16(5):371-379.
DOI: <https://doi.org/10.4244/EIJ-D-20-00052>



CORONARY INTERVENTIONS

Validation of the Academic Research Consortium for High Bleeding Risk (ARC-HBR) criteria in patients undergoing percutaneous coronary intervention and comparison with contemporary bleeding risk scores

EuroIntervention 2020;16:371-379. DOI: 10.4244/EIJ-D-20-00052



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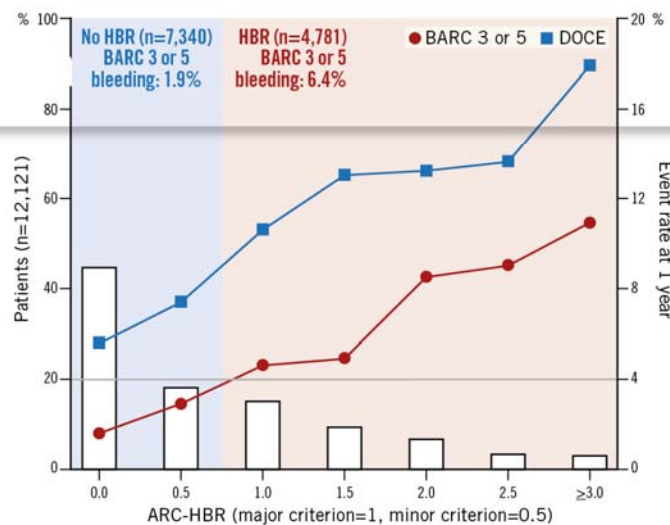
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Aims: The Academic Research Consortium for High Bleeding Risk (ARC-HBR) defined consensus-based criteria for patients at high bleeding risk (HBR) undergoing percutaneous coronary intervention (PCI). We aimed to validate the ARC-HBR criteria for the bleeding outcomes using a large cohort of patients undergoing PCI.

Methods and results: Between 2009 and 2016, patients undergoing PCI were prospectively included in the Bern PCI Registry. Patients were considered to be at HBR if at least one major criterion or two minor criteria were met. The primary endpoint was Bleeding Academic Research Consortium (BARC) 3 or 5 bleeding at one year; ischaemic outcomes were assessed using the device-oriented composite endpoints (DOCE) of cardiac death, target vessel myocardial infarction, and target lesion revascularisation. Among 12,121 patients, those at HBR (n=4,781, 39.4%) had an increased risk of BARC 3 or 5 bleeding (6.4% vs 1.9%; p<0.001) and DOCE (12.5% vs 6.1%; p<0.001) compared with those without HBR. The degree of risk and prognostic value were related to the risk factors composing the criteria. The ARC-HBR criteria had higher sensitivity than the PRECISE-DAPT score and the PARIS bleeding risk score (63.8%, 53.1%, 31.9%), but lower specificity (62.7%, 71.3%, 86.5%) for BARC 3 or 5 bleeding.

Conclusions: Patients at HBR defined by the ARC-HBR criteria had a higher risk of BARC 3 or 5 bleeding as well as DOCE. The bleeding risk was related to its individual components. The ARC-HBR criteria were more sensitive for identifying patients with future bleedings than other contemporary risk scores at the cost of specificity. ClinicalTrials.gov Identifier: NCT02241291





Visual summary. According to the ARC-HBR criteria, 40% of patients undergoing PCI were at HBR. Compared with patients without HBR, those at HBR had an increased risk of BARC 3 or 5 bleeding (6.4% vs 1.9%, $p<0.001$). There was a gradual risk increase for BARC 3 or 5 bleeding and DOCE as a function of the ARC-HBR score. BARC: Bleeding Academic Research Consortium; DOCE: device-oriented composite endpoints; HBR: high bleeding risk.

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